UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/266,803	03/12/99	GLENN G	PM-256865

HM12/0814

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EXAMINER	
EWOLDT, G	
ART UNIT	PAPER NUMBER
1644	18

DATE MAILED: 08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/266,803	Glenn et al.
Examiner	**Art Unit**
G. R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 7, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above, claim(s) *13-15, 25, 26, and 36-40* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-12, 16-24, and 27-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: *Notice to Comply*

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Dr. Gerald R. Ewoldt, Group Art Unit 1644.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2).. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures. Specifically, the tetra-peptide sequence on page 25 is not in sequence compliance.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-12, 16-23, and 29-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,340,588 (of record) or Paul et al. (of record) in view of Marinaro et al. (of record) and the admitted prior art on page 16 of the specification, for the reasons of record set forth in Paper No. 14, mailed 12/07/00. See below.

5. Claims 1-12, 16-24, and 27-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,340,588 (of record or Paul et al. (of record) in view of Kosecka et al. (of record), the admitted prior art on page 16 of the specification, and U.S. Patent No. 5,686,100 (of record) for the reasons of record set forth in Paper No. 14, mailed 12/07/00.

Applicant's arguments, filed 6/07/01, have been fully considered but have not been found persuasive. Applicant argues that the Paul et al. reference actually teaches away from the claimed invention and that, while cholera toxin was a known adjuvant, the references do not teach or suggest the use of ADP-

ribosylating exotoxins as immunostimulants or adjuvants for transcutaneous immunization.

Applicant is incorrect in the assertion that the Paul et al. reference actually teaches away from the claimed invention. The reference is silent in regard the use of adjuvants or immunostimulants. As such, the reference neither teaches, nor teaches away from the use of adjuvants or immunostimulants in transcutaneous immunization. The primary references of the rejection, 5,340,588 and the Paul et al. reference, both teach methods of transcutaneous immunization. The '588 patent additionally teaches the use of adjuvants for an "enhanced effects" in said methods. The secondary references, Marinaro et al., and Kosecka et al., teach the value of cholera toxin (the value of which is derived through the toxin's ADP-ribosylating properties) and pertussis toxin, respectively, as adjuvants. Thus, one of skill in the art at the time of invention would have been motivated to combine the methods taught by the references to perform a more effective, or "enhanced," method of immunization. Regarding an expectation of success, once across the barrier of the skin, one of skill in the art would have had every expectation that an enhanced adjuvant effect would occur given the fact that cholera toxin was known to be effective when administered both mucosally or parenterally, i.e., the only known requirement for cholera toxin efficacy as an adjuvant was the requirement that said toxin actually get into the patient.

Applicant further argues that the prior art does not show the desirability of using ADP-ribosylating agents as the specific adjuvants or immunostimulants. However, as it was well-known in the art that ADP-ribosylating agents were among the most effective adjuvants, their use in the claimed method would have been obvious and considered to be nothing more than routine optimization of the claimed method.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321c may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-4, 6-12, 16-21, and 27-35 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 and 15-29 of U.S. Patent No. 5,910,306, in view of U.S. Patent No. 5,733,572 and in further view of U.S. Patent No. 5,256,422, for the reasons of record as set forth in Paper No. 14, mailed 12/07/00.

Applicant has not argued this rejection, thus, the rejection is maintained.

8. The following are New Grounds for Rejection necessitated by Applicant's amendment, filed 4/09/01.

9. Claims 4 and 22-24 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "to enhance said immune response by penetrating said organism's skin," (claim 4),

B) "or a toxoid derivative thereof," (claims 22-24).

Applicant's amendment, filed 6/07/01, asserts that no new matter has been added, however, specific passages in support of the new amendments to the claims have not been indicated and have not been found by the Examiner.

10. Applicant's newly submitted Form 1449, submitted 6/07/01, comprising an IDS of approximately 300 references, has not been initialed because said references have not been provided. While some of the references may have been provided in previous applications, said references are unavailable to the Examiner.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805 The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Patrick J Nolan

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Patent Examiner
Technology Center 1600
August 9, 2001

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